

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

IN RE NEW ENGLAND COMPOUNDING )  
PHARMACY, INC. PRODUCTS LIABILITY )  
LITIGATION )

MDL No.: 2419  
Dkt. No.: 1:13-md-2419

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THIS DOCUMENT RELATES TO: )

Judge Rya W. Zobel

All cases concerning Specialty Surgery Center, )  
Kenneth R. Lister, M.D., and Kenneth Lister, )  
M.D., P.C. )  
\_\_\_\_\_ )

**SSC DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF MOTION FOR  
SUMMARY JUDGMENT ON THE PLAINTIFFS' CLAIMS FOR STRICT PRODUCT  
LIABILITY**

Defendants, Specialty Surgery Center, PLLC ("SSC"), Kenneth R. Lister, M.D. ("Dr. Lister"), and Kenneth Lister, M.D., P.C. ("Dr. Lister's Practice") (collectively "SSC Defendants"), by and through counsel, submit this Memorandum in Support of their Motion for Summary Judgment on the Plaintiffs' Claims for Strict Product Liability.

**INTRODUCTION**

Vials of fungal contaminated methylprednisolone acetate ("MPA") manufactured by the New England Compounding Company, Inc. d/b/a the New England Compounding Center ("NECC") caused this multi-state outbreak of fungal meningitis. NECC sold contaminated methylprednisolone to SSC, an ambulatory surgery center in Crossville, Tennessee, owned in part by Dr. Lister. Dr. Lister, without knowledge or reason to know of the contamination, and believing that the preservative-free MPA was the best medication for his patients, and those of SSC, administered the MPA as part of epidural steroid injections.

The Plaintiffs allege that the SSC Defendants administered contaminated MPA to SSC patients and assert liability under the Tennessee Healthcare Liability Act (“THCLA”) as well as under the Tennessee Products Liability Act (“TPLA”). The Plaintiffs in this MDL also asserted liability against the Tennessee Defendants<sup>1</sup> under the THCLA and the TPLA. However, on February 29, 2016, after considering arguments by both the Plaintiffs’ Steering Committee (“PSC”) and the Tennessee Defendants, this Court held the THCLA, being the more specific statute, took precedence over the TPLA and, therefore, rendered the TPLA inapplicable in the cases against the Tennessee Defendants. [Docket No. 2700].

Not long after, the PSC filed a Motion for Reconsideration asking the Court to reconsider its February 29<sup>th</sup> Opinion and Order. [Docket No. 2749]. On April 25, 2016, this Court denied that Motion for Reconsideration. [Docket No. 2826]. Therefore, this Court’s February 29<sup>th</sup> Opinion and Order is unquestionably the law of the case on the precise issue now before the Court: whether the THCLA renders the TPLA inapplicable to the SSC Defendants. Santmader Consumer USA Inc. v. Walsh, 762 F.Supp.2d 217, 235 (D. Mass. 2010); In re New England Compounding Pharmacy, Inc., Products Liability Litigation, No. 13-02419-RWZ (May 15, 2014). Application of the February 29<sup>th</sup> Opinion and Order would necessitate a finding that the THCLA renders the TPLA inapplicable to the SSC Defendants.

### **SUMMARY OF ARGUMENT**

The SSC Defendants are seeking this Court to apply the February 29<sup>th</sup> Opinion and Order to the SSC cases as the issues presented to the Court which led to such

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<sup>1</sup> The “Tennessee Defendants” refers to Clinic-Related Defendants located in Tennessee: Saint Thomas Outpatient Neurological Center, LLC (“STOPNC”); Howell Allen Clinic, P.C.; John Culclasure, MD; Debra Schamberg, RN, CNOR; and Vaughan Allen, MD.

decision are identical to the issues presented in the SSC cases. In particular, just as with cases involving the Tennessee Defendants, the complaints and undisputed facts establish that the Plaintiffs allege injuries “related to the provision of ... health care services,” which are governed by the THCLA, “regardless of the theory of liability asserted.” Moreover, as this Court noted in its February 29<sup>th</sup> Opinion and Order:

[A]ny argument that the THCLA does not apply would be unavailing. As discussed above, the THCLA applies to “any civil action... related to... the provision of health care services.” Tenn. Code Ann. § 29-26-101(a)(1) (West 2015). Plaintiffs’ allegations concern the injection of contaminated MPA as a part of pain-treatment services performed by medical professionals, and therefore plainly relate to the provision of health care services.

[Docket No. 2700, n.3].

As this Court is aware, the THCLA does not allow a finding of “faultless liability, and requires that plaintiffs prove some dereliction of a professionally acceptable standard of care.” [Docket No. 2700 (citing Tenn. Code Ann. § 29-26-115(a); Rye v. Women's Care Ctr. of Memphis, M PLLC, 477 S.W.3d 235 (Tenn. 2015))]. As such, under the THCLA, liability for an injury “related to the provision of ... health care services” cannot arise under strict liability in tort. The TPLA, on the other hand, embraces strict liability. Tenn. Code Ann. § 29-28-105(a).

Obviously, and as this Court is aware, this presents a conflict between the liability and damages provisions of the THCLA and the TPLA, which “preclude[s] the application of both, and force[s] a choice between them.” [Docket No. 2700]. As this Court found, however, “[w]hen faced with such conflicts, Tennessee courts apply the more specific statute in lieu of the more general one.” [Docket No. 2700 (citing Graham v. Caples,

325 S.W.3d 578, 582 (Tenn. 2010)]. Applying that to the cases involving the Tennessee Defendants, this Court held

The parties agree that between the TLPA and the THCLA, the THCLA is the more specific statute, and the plaintiffs do not dispute that the THCLA applies in these cases. The THCLA therefore takes precedence, rendering the TLPA inapplicable in these cases. Because the TLPA cannot apply here, I need not and do not address the question of whether it applies to St. Thomas.”

[Docket No. 2700]<sup>2</sup>. As the THCLA also clearly applies in the SSC cases, this Court should likewise find the THCLA renders the TPLA inapplicable in the SSC cases, and render summary judgment on same in favor of the SSC Defendants.<sup>3</sup>

### **STANDARD OF REVIEW**

Summary judgment is proper where no genuine issue of material fact exists and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56. The moving party is entitled to summary judgment if it demonstrates that there is no genuine dispute as to a material fact and that it is entitled to judgment as a matter of law. Id.

“A genuine issue of material fact does not spring into being simply because a litigant claims that one exists.” Griggs-Ryan v. Smith, 904 F.2d 112, 115 (1<sup>st</sup> Cir. 1990). After the moving party properly presents evidence negating an essential element of the non-movant’s claim, the non-movant cannot simply rely on conclusory responses unsupported by the evidence. Id. at 115 (citing Ayer v. United States, 902 F.2d 1038, 1044-45 (1<sup>st</sup> Cir. 1990)). In fact, the non-movant may only defeat the motion if he sets forth specific facts that present a genuine issue for trial. See Fed. R. Civ. P. 56. In

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<sup>2</sup> This holding was reaffirmed in this Court’s April 25, 2016 Order wherein it denied the PSC’s Motion for Reconsideration. [See Docket No. 2826].

<sup>3</sup> In the February 29<sup>th</sup> Opinion and Order, this Court did not find it necessary to address the question of whether the TPLA applied to STOPNC “[b]ecause the TLPA cannot apply here.” [Docket No. 2700]. Therefore, this motion does not address whether the TPLA applies to the SSC Defendants.

other words, the non-movant must “demonstrate that a trial worthy issue exists.” Mulvihill v. Top-Flite Golf Co., 335 F.3d 15, 19 (1<sup>st</sup> Cir. 2003); see also Docket No. 2700.

### **LAW AND ARGUMENT**

Here, the undisputed facts demonstrate that the Plaintiffs’ claims “relate[ ] to the provision of ... health care services,” Tenn. Code Ann. § 29-26-101, and as such are subject to the THCLA, regardless of the theory of liability on which the Plaintiffs’ action is based. Therefore, this Court should apply the February 29<sup>th</sup> Opinion and Order to the SSC cases.

#### **I. The undisputed facts establish that the Plaintiffs’ claims are governed by the THCLA.**

“The THCLA governs ‘any civil action ... related to ... the provision of health care services.’” [Docket No. 2700 (citing Tenn. Code Ann. § 29-26-101(a)(1))]. By statute:

Health care services to persons includes care by health care providers, which includes care by physicians, nurses, licensed practical nurses, pharmacists, pharmacy interns or pharmacy technicians under the supervision of a pharmacist, orderlies, certified nursing assistants, advance practice nurses, physician assistants, nursing technicians and other agents, employees and representatives of the provider, and also includes staffing, custodial or basic care, positioning, hydration and similar patient services.

Tenn. Code Ann. § 29-26-101(b). Clearly, the care provided by the SSC Defendants to the Plaintiffs falls within this statutory definition. SUMF 1-6. The Plaintiffs sought care and medical treatment from the SSC Defendants, and underwent epidural steroid injections at SSC (an AAAHC accredited health care facility), which were performed by Dr. Lister (a licensed anesthesiologist). SUMF 5-6.

The Plaintiffs even admit as much in their complaints, wherein they allege they “sought treatment from the Clinic Related Defendants” (which was defined to include

SSC) and, as part of that medical treatment, “the Clinic Related Defendants injected MPA directly into patients’, including the Plaintiffs’ spinal canals...” 2<sup>nd</sup> Am. Master Compl., ¶ 151-154 [Docket No. 1719]. Therefore, there is no reasonable dispute as to whether the SSC Defendants provided health care services to the Plaintiffs; obviously, they did.

Similarly, there is no reasonable dispute as to whether the Plaintiffs allege injury “related to” the health care services provided by the SSC Defendants. In their complaints, the Plaintiffs unquestionably allege the health care services provided by the SSC Defendants caused serious injury and/or death to the Plaintiffs. 2<sup>nd</sup> Am. Master Compl., ¶ 151-154; 206 [Docket No. 1719]. Specifically, they allege that they sought medical treatment, they were administered NECC drugs as part of that medical treatment, and they were injured as a result. 2<sup>nd</sup> Am. Master Compl., ¶ 151-154; 206 [Docket No. 1719]. Thus, by their own allegations, the Plaintiffs cannot escape the wide grasp of the THCLA.

Even ignoring the Plaintiffs’ unambiguous admissions in the complaints, the injection of the MPA into the Plaintiffs during the epidural steroid injections cannot be separated from treatment of the Plaintiffs; the injection of the medication was clearly an intended element of such treatment. The MPA was injected into the epidural space of Plaintiffs as part of epidural steroid injections performed by a licensed anesthesiologist at an AAAHC accredited health care facility healthcare facility. SUMF 1-6. Without the injection of the MPA during and as part of the care and treatment performed by the SSC Defendants, the Plaintiffs would not have suffered injury. The Plaintiffs, therefore,

cannot reasonably claim their injuries do not relate to the provision of health care services. Moreover, as this Court even noted:

[A]ny argument that the THCLA does not apply would be unavailing. As discussed above, the THCLA applies to “any civil action... related to... the provision of health care services.” Tenn. Code Ann. § 29-26-101(a)(1) (West 2015). **Plaintiffs’ allegations concern the injection of contaminated MPA as a part of pain-treatment services performed by medical professionals, and therefore plainly relate to the provision of health care services.**

[Docket No. 2700, n.3 (emphasis added)].

Again, the THCLA governs any claim for injury “related to” the provision of health care services. Tenn. Code Ann. § 29-26-101. Obviously, the administration of the MPA “related to” the provision of health care services provided by the SSC Defendants. This requires application of the THCLA.

## **II. The TPLA is inapplicable in these cases.**

Just as with the cases involving the Tennessee Defendants, the complaints and undisputed facts clearly establish that the THCLA applies to the Plaintiffs’ claims. As this Court is aware (and has held), the THCLA does not allow a finding of “faultless liability, and requires that plaintiffs prove some dereliction of a professionally acceptable standard of care.” See [Docket No. 2700 (citing Tenn. Code Ann. § 29-26-115(a); Rye v. Women's Care Ctr. of Memphis, M PLLC, 477 S.W.3d 235 (Tenn. 2015))]. As such, liability for an injury “related to the provision of ... health care services” cannot arise under strict liability in tort. The TPLA, on the other hand, embraces strict liability. Tenn. Code Ann. § 29-28-105(a).

Obviously, and as this Court found, this presents a conflict between the liability and damages provisions of the THCLA and the TPLA, which “preclude[s] the application

of both, and force[s] a choice between them.” [Docket No. 2700]. As this Court found, however, “[w]hen faced with such conflicts, Tennessee courts apply the more specific statute in lieu of the more general one.” [Docket No. 2700]; Graham v. Caples, 325 S.W.3d 578, 582 (Tenn. 2010). Applying that to the cases involving the Tennessee Defendants, this Court held

The parties agree that between the TLPA and the THCLA, the THCLA is the more specific statute, and the plaintiffs do not dispute that the THCLA applies in these cases. The THCLA therefore takes precedence, rendering the TLPA inapplicable in these cases. Because the TLPA cannot apply here, I need not and do not address the question of whether it applies to St. Thomas.”

[Docket No. 2700]<sup>4</sup>. This holding is equally applicable to the SSC Defendants. As demonstrated above, the undisputed facts clearly demonstrate the Plaintiffs’ claims against the SSC Defendants plainly relate to the provision of health care services. As such, the THCLA applies to the Plaintiffs’ claims against the SSC Defendants just as it applied to the Plaintiffs’ claims against the Tennessee Defendants. Tenn. Code Ann. § 29-26-101. Therefore, this Court should likewise rule the THCLA renders the TPLA inapplicable in the SSC cases and render summary judgment on same in favor of the SSC Defendants.

### **CONCLUSION**

Based on the foregoing, the SSC Defendants respectfully request an Order granting their Motion for Summary Judgment on the Plaintiffs’ Claims for Strict Product Liability.

Respectfully submitted,

/s/ Parks T. Chastain

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<sup>4</sup> This holding was reaffirmed in this Court’s April 25, 2016 Order wherein it denied the PSC’s Motion for Reconsideration. [See Docket No. 2826].



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### **CERTIFICATE OF SERVICE**

I hereby certify that this document filed through the CM/ECF system will be served electronically to the registered participants identified on the Notice of Electronic Filing and copies will be served via electronic mail or regular US mail to those participants identified as unregistered this the 19th day of May, 2016.

/s/ Parks T. Chastain

**PARKS T. CHASTAIN**

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\* Admitted *pro hac vice*

\*\* Admitted pursuant to MDL Order No. 1

\*\*\* Admitted *pro hac vice*